To Dane Henney M.D,

1836 '99 SEP -9

Please approve claims filed for saw palmetto ~~for~~ ~~AUG 19~~ symptoms of benign prostatic hyperplasia, psyllium husk seed & the risk of heart disease, folic acid, V B6 & B 12 & cardiovascular disease, & Vit E & the risk of cardiovascular disease, I'm sick & tired of FDA telling me what I can or not can to do. I've been on all these supps for years, I'm 71 & doing great. I'm healthy due to above Vit's. Why doesn't the FDA investigate all the deaths due to drugs. I understand those deaths are the 4th or 5th killer of people. You are falling behind in your job -

Mrs. E. Kudlicki

99P-3029 C154

It Took Fours Years for Folic Acid Claims

Despite this recommendation, the FDA prohibited vitamin manufacturers from printing this claim on bottles of supplements containing folic acid. The agency finally reversed itself in 1996, relenting only under growing political pressure from Senator Orrin Hatch and Congressman Bill Richardson. However, during those four years, the FDA's unreasonable refusal to permit this folic acid claim where it could do the most good contributed to an estimated 10,000 neural tube birth defects! Imagine, 10,000 children and their families suffer the consequences of these tragic birth defects—which could have been prevented, had the FDA acted in a timely manner.

It gets even worse. The FDA actually squelched efforts of a state agency to improve the health of its citizens. The Texas Department of Public Health recognized in 1992 that in Cameron County, an impoverished rural county in southern Texas, the incidence of ***spina bifida*** and neural tube defects was quite high. They put together a program to disseminate information on the prevention of these birth defects and to supply folic acid to women at risk. Incredibly, the FDA intervened, and this very important program was delayed for four years.

Other Speakers Called for Responsible FDA Action

Representative DeFazio implored fairness on the part of the FDA. "We are here today to begin to turn the tide and say we are going to provide useful information. The FDA should go back and do what it's supposed to do, which is regulate in the public interest—not in the interest of some certain special interest." Drug Co.

CROSS FILE SHEET

File Number: 99P-3029/C154

See File Number: 99P-3030/C154

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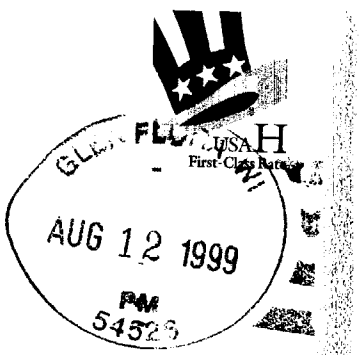

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